

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIOGEN INTERNATIONAL GMBH)
and BIOGEN MA INC.,)
)
Plaintiffs,)
)
v.) C.A. No. 17-823-LPS
) (Consolidated)
AMNEAL PHARMACEUTICALS LLC,)
) C.A. No. 17-874-LPS
Defendant.)
)

STIPULATION OF INFRINGEMENT BY SANDOZ AND PRINSTON

WHEREAS Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, “Biogen”) assert that Defendants Sandoz Inc. (“Sandoz”) and Princeton Pharmaceutical Inc. (“Princeton”) infringe claims 1-4, 6, 8-13, 15, and 16 of U.S. Patent No. 8,399,514 (“the ’514 patent”) (collectively, the “Asserted Claims” of the “Asserted Patent”) by submitting, or causing to be submitted, Abbreviated New Drug Application No. 210414 seeking approval to engage in the commercial manufacture, use, import, sale, or offer to sell generic capsules containing dimethyl fumarate (“the ANDA Products”), which if approved and marketed, will infringe the Asserted Claims;

WHEREAS claims 5, 7, 14, and 17-20 of the ’514 patent have not been asserted;

WHEREAS, Biogen brought *Biogen International GmbH, et al. v. Sandoz Inc.*, C.A. No. 17-874-LPS (“the 17-874 Action”), which is one of the component cases in the above-captioned consolidated action (C.A. No. 17-823-LPS) (the “Consolidated Action”), and in which Biogen alleged infringement by Sandoz of the Asserted Claims of the Asserted Patent based Sandoz’s filing of ANDA No. 210414;

WHEREAS, Biogen also brought *Biogen MA Inc. v. Prinston Pharmaceutical Inc.*, C.A. No. 17-827-LPS (“the Prinston Action”), which was one of the component cases in the Consolidated Action, and in which Biogen alleged infringement by Prinston of the Asserted Claims of the Asserted Patent based on Prinston’s filing of ANDA No. 210512;

WHEREAS Biogen and Prinston stipulated to dismissal of all claims and counterclaims brought in the Prinston Action on September 7, 2018 (*see* D.I. 172 in the Consolidated Action);

WHEREAS, Sandoz and Prinston consented to the joinder of Prinston in the 17-874 Action (*see* D.I. 180 in the Consolidated Action);

WHEREAS, ANDA No. 210414 contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the Asserted Patent is invalid, unenforceable, or would not be infringed by the commercial manufacture, use, or sale of the accused ANDA Products;

WHEREAS, Sandoz and Prinston deny that the commercial marketing and sale of the ANDA Products would infringe any valid and enforceable claims asserted in this case but desire to streamline the issues at trial;

NOW THEREFORE, Biogen, Sandoz and Prinston, by their undersigned counsel, STIPULATE as follows:

1. For purposes of the Consolidated Action only (but including the underlying 17-874 Action which is a component case thereof) only, Sandoz and Prinston stipulate that the submission of ANDA No. 210414 constitutes infringement of the Asserted Claims pursuant to 35 U.S.C. § 271(e)(2)(A), provided those claims are not proven invalid or unenforceable. Sandoz and Prinston further stipulate that the commercial manufacture, use, sale, offer to sell, and/or importation of the ANDA Products prior to the expiration of the Asserted Patent in accordance

with the labeling proposed in ANDA No. 210414 would further infringe the Asserted Claims pursuant to 35 U.S.C. § 271, provided those claims are not proven invalid or unenforceable.

2. By entering into this Stipulation, Sandoz and Prinston do not waive any invalidity defenses they have raised. This Stipulation shall not be used to argue that claims satisfy the definiteness requirements of 35 U.S.C. § 112, or for any other purpose other than the issue of infringement. This Stipulation may not be used or admitted in any proceeding other than the Consolidated Action (including the underlying 17-874 Action) against Sandoz and Prinston concerning ANDA No. 210414.

3. The parties reserve all other claims and defenses.

IT IS HEREBY STIPULATED:

Dated: October 25, 2019

ASHBY & GEDDES

/s/ Andrew C. Mayo

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*Attorneys for Defendants Sandoz Inc. and
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SO ORDERED, this _____ day of _____, 2019

Chief Judge